

Guidance document
SwissGMDP Database

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1 Introduction

This guidance document advises companies, authorities and individuals on how to use the **SwissGMDP database** – searching for specific establishment licence holders and sites, accessing and sharing information, obtaining GMP/GDP certificates and exporting establishment licence holder data.

This guidance document aims to offer an overview of and guidance on the SwissGMDP database functions for companies, authorities and individuals.

1.1 Overview

The Swiss Agency for Therapeutic Products (Swissmedic) has launched SwissGMDP, a new database aimed at simplifying the sharing of information regarding compliance with good manufacturing practice (GMP) and good distribution practice (GDP) of Swiss companies. SwissGMDP serves as a centralised platform listing GMP and GDP certificates for all companies in Switzerland holding valid establishment licences issued by Swissmedic. This allows companies, authorities and individuals to easily check GMP/GDP status.

1.2 Key features of SwissGMDP

- Provides free access to electronic GMP/GDP certificates which also includes Switzerland-specific operations.
- Lists all operations of a site issued by Swissmedic incl. those that do not qualify for GDP/GMP certificates.
- Allows you to easily search for establishment licence holders and sites.
- Create an Excel list of your specific searches or simply download data for all sites.
- Enhances information exchange among regulatory authorities, the pharmaceutical industry and the general public.
- Helps to protect the medicinal product distribution chain and the active substance supply chain by making it easier to check legitimate players.

With SwissGMDP, companies can save significantly on costs for issuing GMP/GDP certificates, as all certificates are provided free of charge. To maintain the SwissGMDP database, a fee will only be charged for each request or inspection-driven update of the GMP/GDP relevant data.

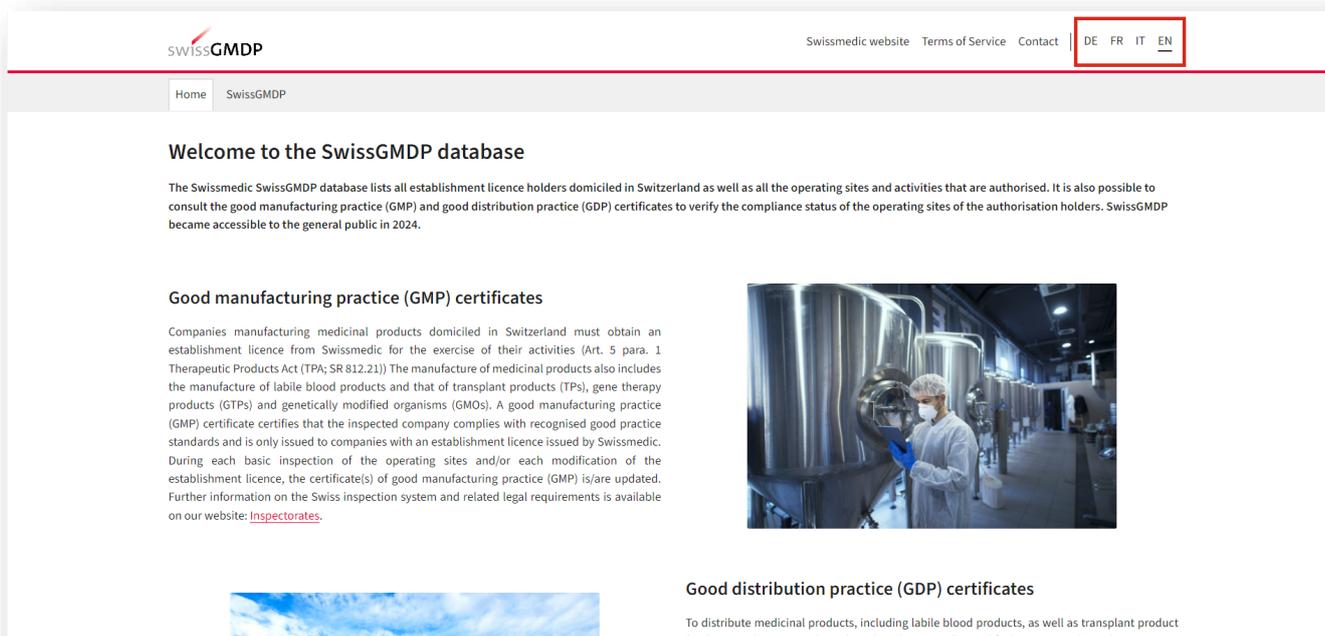
1.3 Abbreviations

GDP	Good Distribution Practice
GMP	Genetically Modified Organisms
GMP	Good Manufacturing Practice
GMPF	Good Manufacturing Practice for medicated Feed
GT	Gene Therapy products
MP	Medicinal Products incl. blood
TP	Transplant Products (within SwissGMDP TP comprises TP, GT and GMO)
TPA	Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, SR 812.21)
WL	<i>Wegleitung</i> = guidance document

2 How to use the SwissGMDP database

2.1 Accessing the SwissGMDP database

To access the SwissGMDP database, simply open swissgmdp.ch in your web browser.

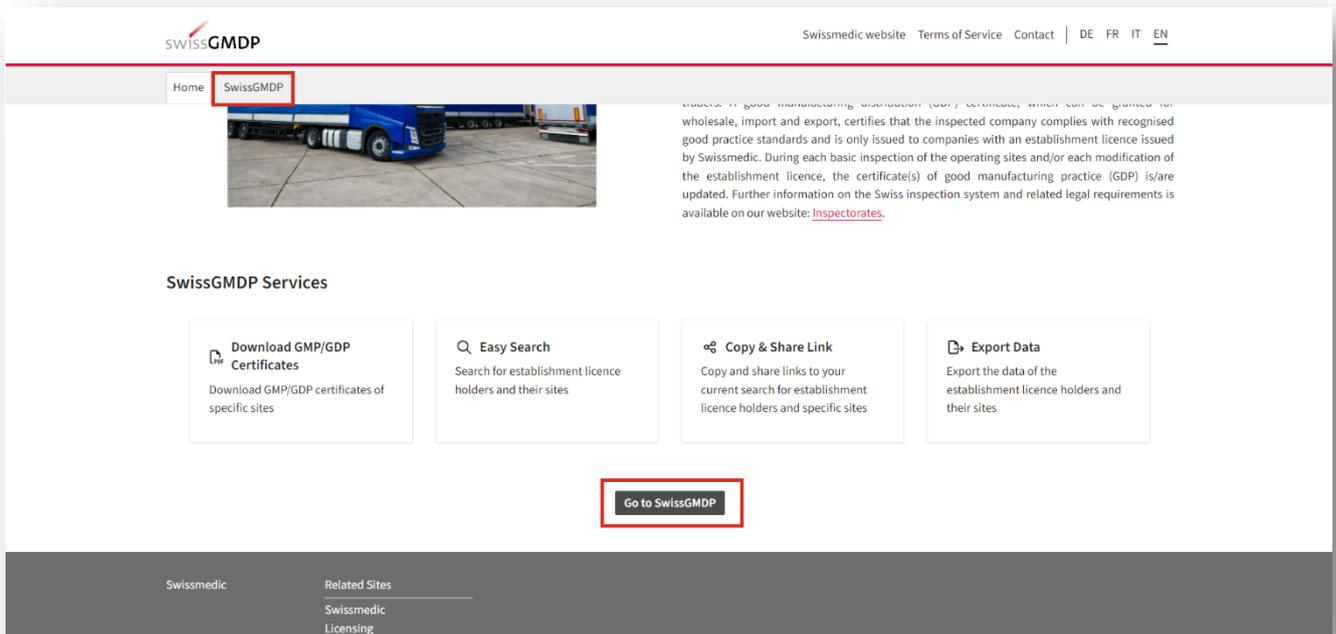


The screenshot shows the SwissGMDP database homepage. At the top, there is a navigation bar with the SwissGMDP logo on the left and links for 'Swissmedic website', 'Terms of Service', 'Contact', and a language switcher with options for 'DE', 'FR', 'IT', and 'EN'. Below the navigation bar, there is a 'Home' button and a 'SwissGMDP' tab. The main content area features a 'Welcome to the SwissGMDP database' section with a brief description of the database's purpose. Below this, there are two main sections: 'Good manufacturing practice (GMP) certificates' and 'Good distribution practice (GDP) certificates'. The GMP section includes a detailed paragraph about the requirements for manufacturing medicinal products and a link to 'Inspectorates'. The GDP section includes a paragraph about distributing medicinal products. There are also images: a person in a lab coat working in a pharmaceutical facility and a blue sky with clouds.

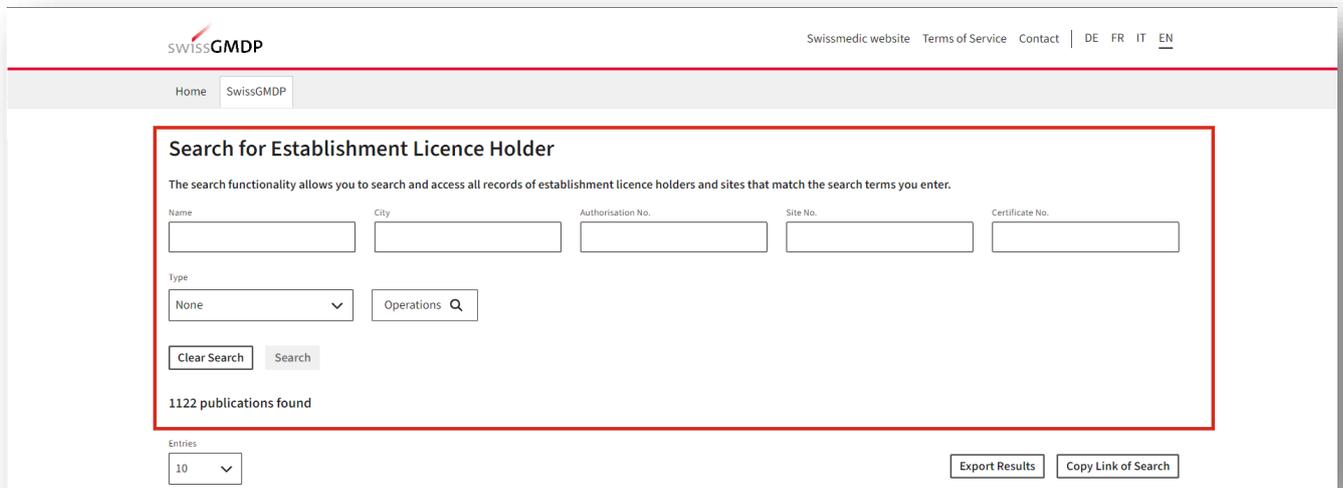
On the homepage you will find detailed information about the database and its services. The SwissGMDP database is available in German, French, Italian and English. You can choose your preferred language using the language switcher located in the header.

No login account is required in order to use the SwissGMDP database, as it is freely accessible to the general public. Accessing the core functions of SwissGMDP is simple.

1. Click the *SwissGMDP* tab in the navigation bar or;
2. Use the *Go to SwissGMDP* button at the bottom of the landing page.



After clicking the button you will land on the SwissGMDP page, where you will find a search panel featuring various filters.



Below the panel, you will find all published establishment licence holders displayed in a card format (1). Each card represents an establishment licence holder and includes details such as the name, authorisation number and type. Additionally, each card contains a collapsible section. By clicking the arrow next to the subtitle *Sites*, you can expand this section (2). When expanded, detailed site information such as site number, certificate number and compliance status is displayed.

The default number of card entries is set to ten. However, you have the option of expanding the list by selecting from the dropdown labelled *Entries* (3). This allows you to display 25 or 50 entries.

1122 publications found

Entries 3 Export Results Copy Link of Search

Test AG 1

Authorisation No.: 500000-123456789 Type: Medicinal Products incl. blood (MP) Address: Hallerstrasse 7 Postal Code: 3012 City: Bern

Sites 2

Site No.	Name	Address	Postal Code	City	Certificate No.	Compliance Status	Actions
1234567	Test AG Site	Hallerstrasse 7	3012	Bern	1001234	✓	👁️ ⬇️

Test AG 2

Authorisation No.: 510000-123456789 Type: Transplant products (TP) Address: Erlachstrasse 8 Postal Code: 3012 City: Bern

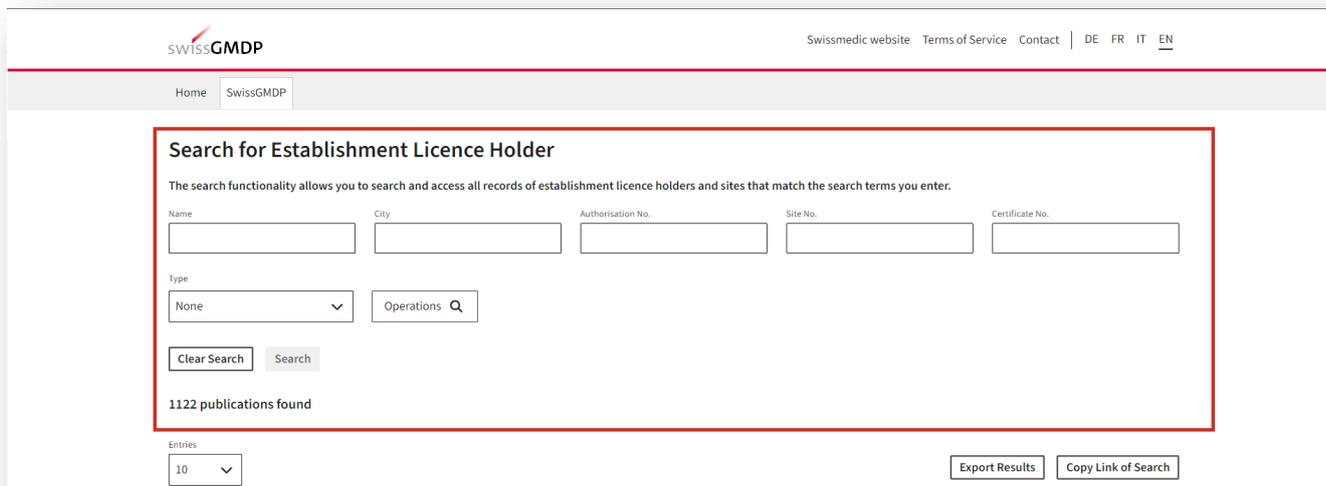
Sites >

2.2 Search for establishment licence holders and sites

2.2.1 General search

The search function in the SwissGMDP database provides an intuitive way to find specific establishment licence holders or sites. You can use various search filters to refine your search, including:

- **Name:** Search for establishment licence holders or their sites by name.
- **City:** Search for establishment licence holders or their sites by city.
- **Authorisation No.:** Search for establishment licence holders by their authorisation number, which comprises 15 digits.
- **Site No.:** Search for sites by their site number, which consists of seven digits.
- **Certificate No.:** Search for certificates by their certificate number, which consists of seven digits.
- **Type:** Filter by type of the establishment licence holder, choosing between “Medicinal products incl. blood” (MP) or “Transplant products” (TP).
- **Operations:** Filter by authorised operations of the establishment licence holder and their sites.



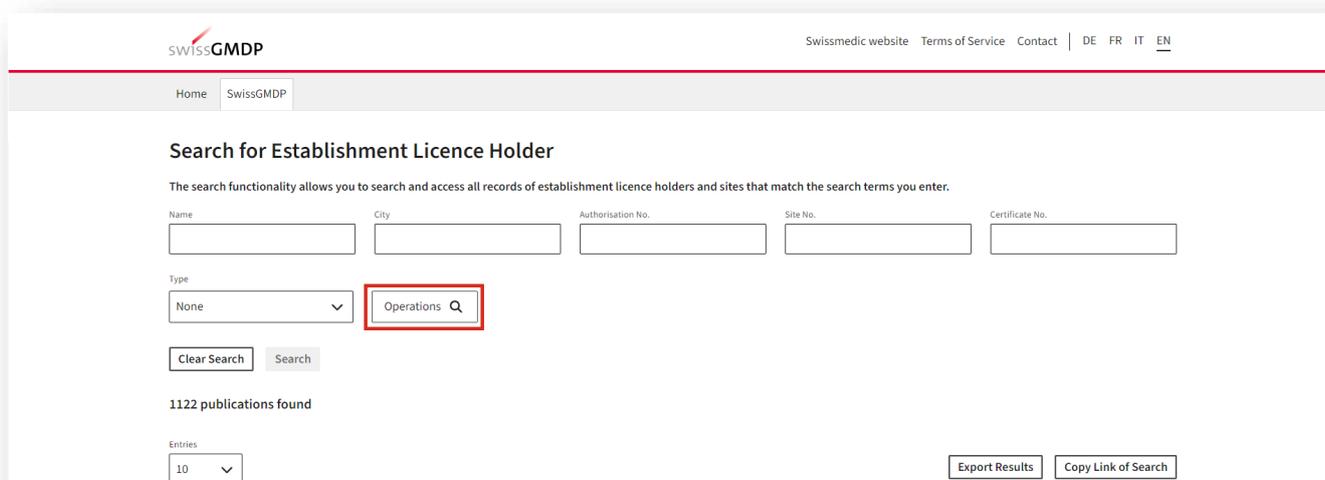
After entering the search term (imprecise search (wildcard search) without “*” possible), click on the *Search* button or press *Enter*. Matching values will be highlighted for easy identification. If your search term matches a site, an information text reading *Sites - Match found inside collapsible section* will appear, indicating the matched value within the site details.

To clear all filters and reset the search results, simply click the *Clear Search* button. This action will reset all entered and selected filters, restoring the search result list to its original state.

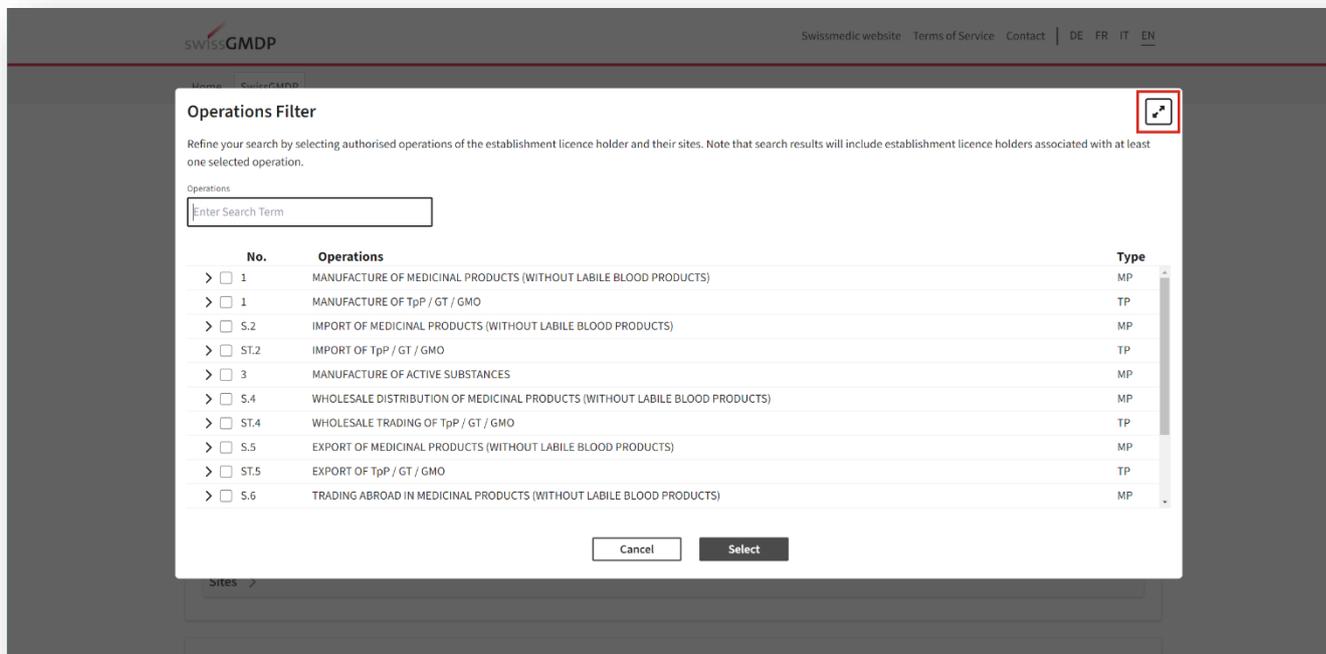
2.2.2 Filter by operations

To filter by authorised operations of the establishment licence holder and their sites:

1. Click on the *Operations* button.



This action will open a modal that displays all available operations. You can expand the modal by clicking the expand action button located in the top right corner, and collapse it by clicking the same button again.

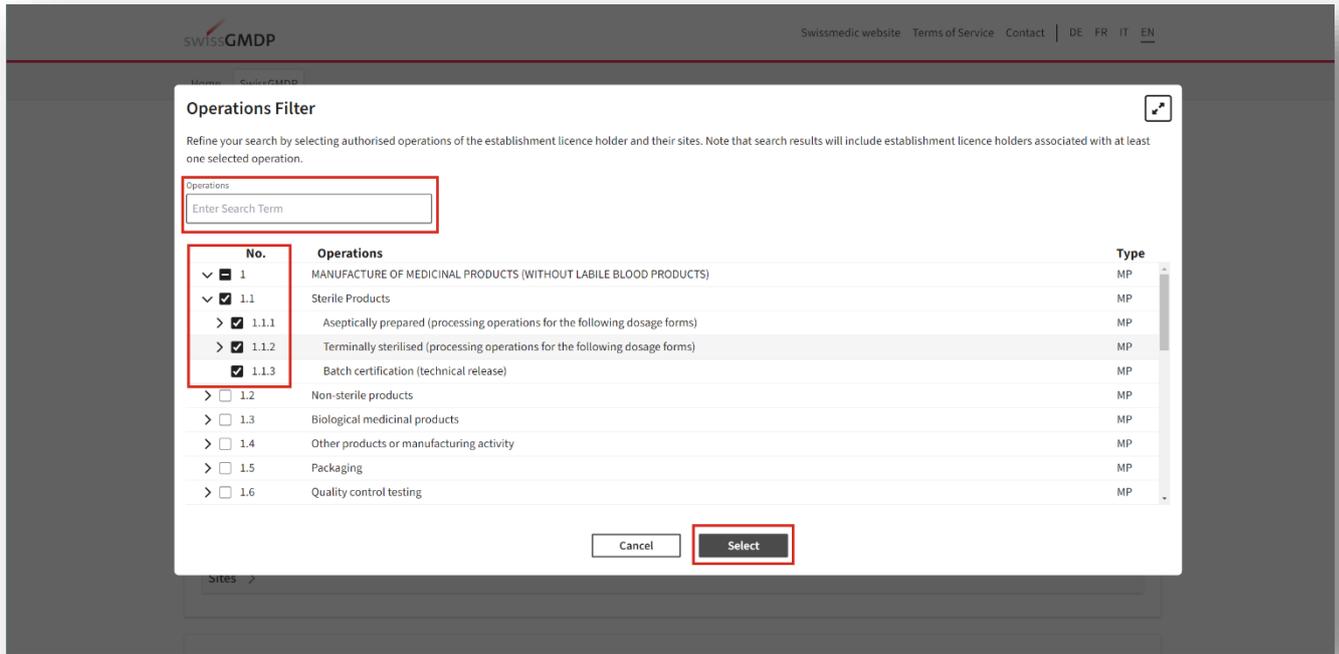


Note:

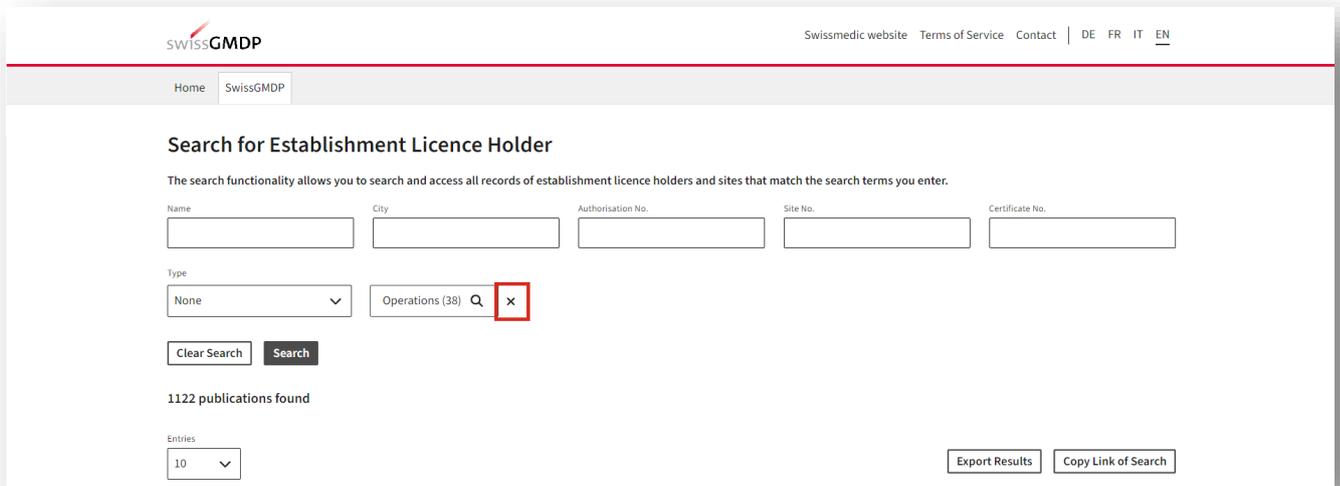
Authorised operations are only available in English. By default, all operation options are displayed. Upon selecting a type (e.g. MP or TP), only operations corresponding to the selected type will be shown.

The suffix “S” refers to operations not covered by the Mutual Recognition Agreement between Switzerland and the EU for Medicinal Products, whereas the suffix “ST” refers to operations not covered by the Mutual Recognition Agreement between Switzerland and the EU for Advanced Therapeutic Medicinal Products.

2. Use the search input field to find specific operations by entering a search term and/or select desired operations by checking the checkboxes.
3. Once all desired operations have been selected, click the *Select* button to save and close the modal.
4. Press the *Search* button to search for your selection.

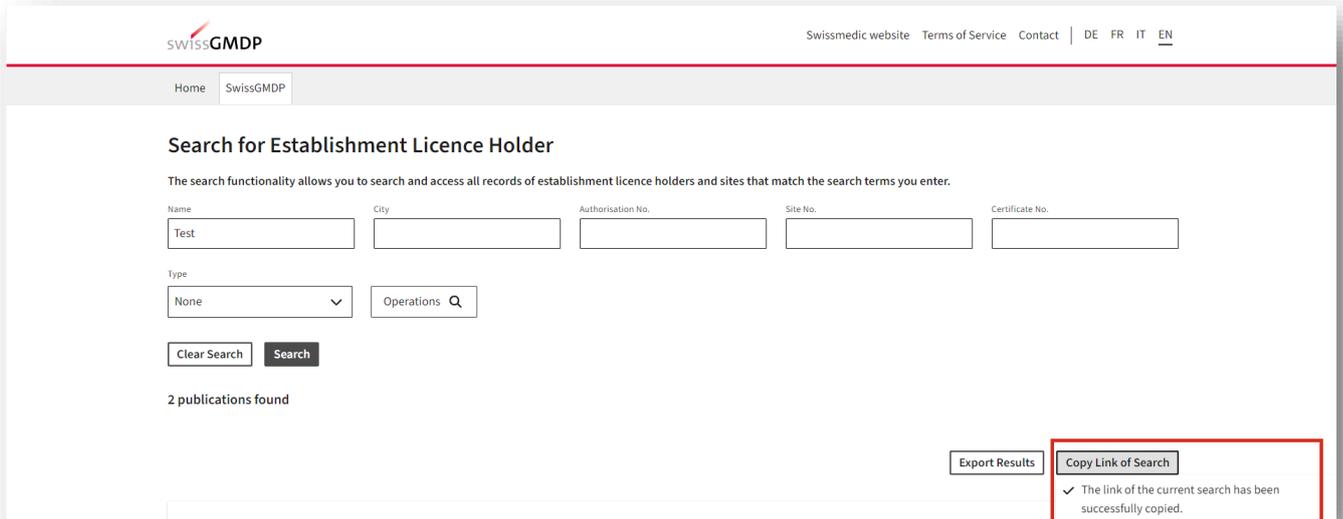


5. To clear the selected operations, click the X button next to the “Operations” button.



2.3 Copy & share link of your search

To share your current search for establishment licence holders and their sites with others, you can use the *Copy Link of Search* button. This feature enables you to copy the link to your search, including all entered search criteria and parameters, directly to your clipboard. This simplifies the process of sharing links to your search results with collaborators for easy reproduction.

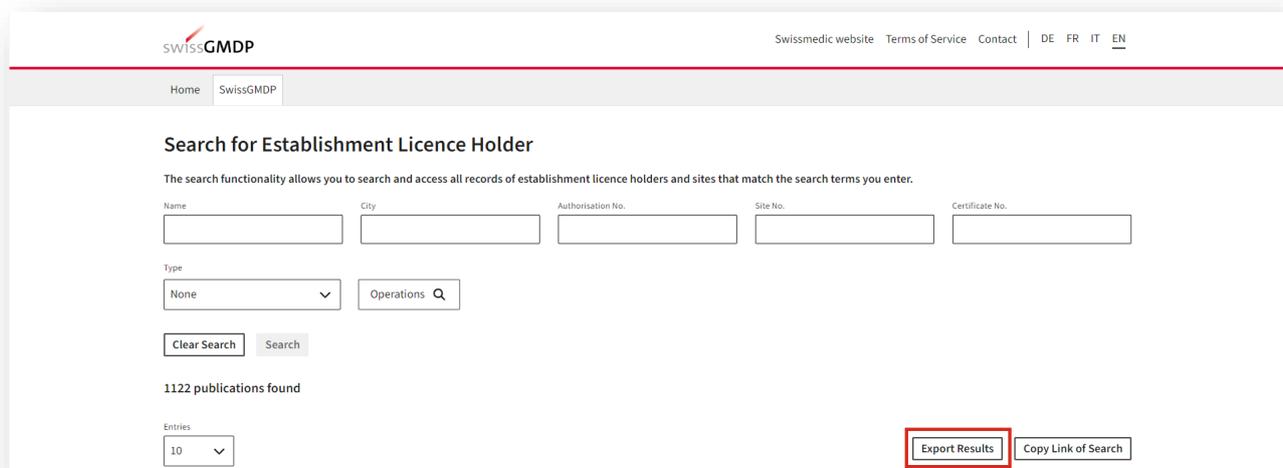


The screenshot shows the SWISSGMDP search interface. At the top, there is a navigation bar with the SWISSGMDP logo and links for 'Swissmedic website', 'Terms of Service', 'Contact', and language options 'DE', 'FR', 'IT', 'EN'. Below this is a breadcrumb trail with 'Home' and 'SwissGMDP'. The main heading is 'Search for Establishment Licence Holder'. A sub-heading states: 'The search functionality allows you to search and access all records of establishment licence holders and sites that match the search terms you enter.' The search form includes input fields for 'Name' (containing 'Test'), 'City', 'Authorisation No.', 'Site No.', and 'Certificate No.'. There is a 'Type' dropdown menu set to 'None' and an 'Operations' button with a magnifying glass icon. Below the form are 'Clear Search' and 'Search' buttons. The results section shows '2 publications found'. At the bottom right, there are two buttons: 'Export Results' and 'Copy Link of Search'. The 'Copy Link of Search' button is highlighted with a red box, and a confirmation message is displayed below it: '✓ The link of the current search has been successfully copied.'

2.4 Export establishment licence holder data

The SwissGMDP database provides the option of exporting establishment licence holders and their site data. Simply click on the *Export Results* button to start the export process.

If your search results encompass establishment licence holders from both types, two XLSX files will be generated: one for Medicinal Products incl. blood and one for Transplant Products. In cases where the search results include only one type, the corresponding XLSX file will be generated. Additionally, if no search has been conducted and you click the button, all published establishment licence holders will be exported, resulting in two XLSX files.



The screenshot shows the 'Search for Establishment Licence Holder' page on the SwissGMDP website. The page includes a search form with fields for Name, City, Authorisation No., Site No., and Certificate No. Below these fields is a 'Type' dropdown menu set to 'None' and an 'Operations' button with a magnifying glass icon. There are also 'Clear Search' and 'Search' buttons. The search results section shows '1122 publications found' and an 'Entries' dropdown menu set to '10'. The 'Export Results' button is highlighted with a red box, and a 'Copy Link of Search' button is visible next to it.

2.5 Download certificate document

There are two methods for downloading a certificate document:

1. Within the collapsible section, you will find a *Download Certificate(s)* action button for each site.

Export Results Copy Link of Search

Test AG 3

Authorisation No.: 520000-123456789 Type: Medicinal Products incl. blood (MP) Address: Hallerstrasse 7 Postal Code: 3012 City: Bern

Sites - Match Found Inside Collapsible Section

Site No.	Name	Address	Postal Code	City	Certificate No.	Compliance Status	Actions
1112345	Test AG 3	Hallerstrasse 7	3012	Bern	7654321	✓	🔍 ⬇️
1234112	Test AG 3	Erlachstrasse 8	3012	Bern	1001515	✓	🔍 ⬇️
1312123	Test AG 3	Freiburgstrasse 139	3008	Bern	1100777	✓	🔍 ⬇️

2. Within the detail view of a site, you will find a *Download Certificate(s)* button for the respective site.

SWISSGMDP Swissmedic website Terms of Service Contact | DE FR IT EN

Home SwissGMDP

Test AG 3 Copy Link Download Certificate(s)

Establishment Licence Holder Details

Name
Test AG 3

Address
Hallerstrasse 7

Postal Code
3012

City
Bern

Authorisation Number
520000-123456789

Type
Medicinal Products incl. blood (MP)

Site Details

Name
Test AG 3

Address
Erlachstrasse 8

Postal Code
3012

City
Bern

Site Number
1234112

Certificate Number
1001515

Date of last inspection (dd.mm.yyyy)
25.05.2022

Compliance Status
✓ Compliant

Clicking on one of these buttons will trigger a modal to appear, allowing you to select the available certificate documents for the chosen site. Once you have made your selections, simply click the *Download* button, and the chosen certificate documents will be generated and downloadable in PDF format. The PDF name refers to the type, the establishment licence holder, the site number and the date of download.

1 publication found

Download certificate document(s) of Site No. 1234112

Please select the certificate document(s) you want to download of the selected site.

Good Distribution Practice (GDP)

Good Manufacturing Practice (GMP)

Export Results Copy Link of Search

Test AG 3

Authorisation No.: 520000-123456789 Type: Medicinal Products incl. blood (MP) Address: Hallerstrasse 7 Postal Code: 3012 City: Bern

Sites - Match Found Inside Collapsible Section ▾

Site No.	Name	Address	Postal Code	City	Certificate No.	Compliance Status	Actions
1112345	Test AG 3	Hallerstrasse 7	3012	Bern	7654321	✓	👁️ ⬇️
1234112	Test AG 3	Erlachstrasse 8	3012	Bern	1001515	✓	👁️ ⬇️
1312123	Test AG 3	Freiburgstrasse 139	3008	Bern	1100777	✓	👁️ ⬇️

Note:

- Certificate documents, including GMP, GDP, and GMPF¹, are available only in English.
- Downloading certificate documents for sites with the compliance status "Non compliant" is not possible.
- Certain Swiss-specific operations are not GMP- or GDP-relevant² and are not included in a certificate document, or if a site owns only those operations, the generation of a certificate document is not possible.

¹ GMP for Medicated Feed

² All operations relating to the following areas: Trading abroad, Broker or agent, Contract manufacture according to art. 9 para. 2bis TPA of medicinal products not subject to marketing authorisation, Manufacture of medicinal products not subject to marketing authorisation according to art. 9 para. 2 a-cbis TPA for the supply to own clients and operation "S.1.11 Filling and labelling of starting materials with container-specific guarantee of their identity according to chapter 20.1.6.4 Ph.Helv. for the manufacture of medicinal products not subject to marketing authorisation according to art. 9 para. 2 a - cbis TPA"

2.6 Link and QR code in the certificate documents

The link as well as the QR code in each certificate document refers to the detail view of the respective establishment licence holder site (see chapter 2.8).

1. Link in the certificate document



2. QR code provided in the certificate document.

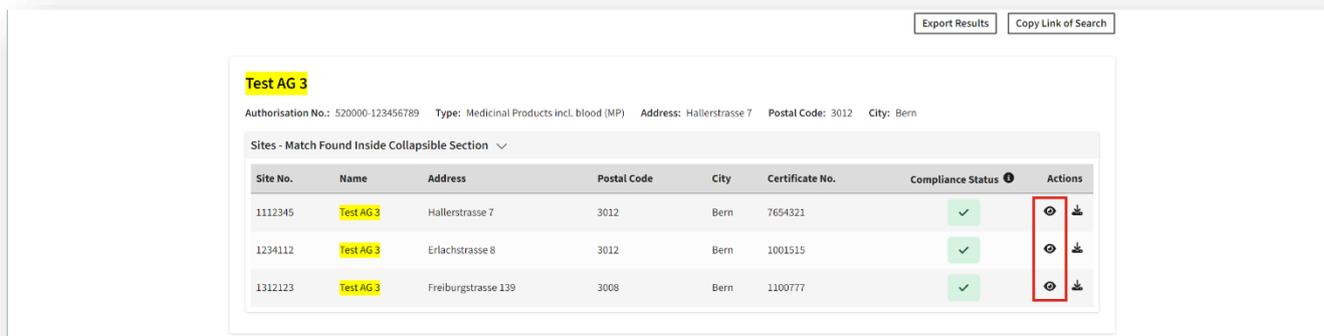


In addition to direct forwarding to SwissGMDP, the validity of this certificate can be checked via the link and the QR code. The seven-digit certificate number (**xxxxxxx**) indicated in the detail view is reflected in the certificate number at the end of the PDF certificate (No. GDP/GMP/GMPF-CH-**xxxxxxx**). If the certificate number in the detail view differs from the number in the downloaded PDF, the certificate is no longer valid.

2.7 View details of an establishment licence holder site

You have three options for accessing the detailed view:

1. By clicking the *View Details* action button within the collapsible section;



Export Results Copy Link of Search

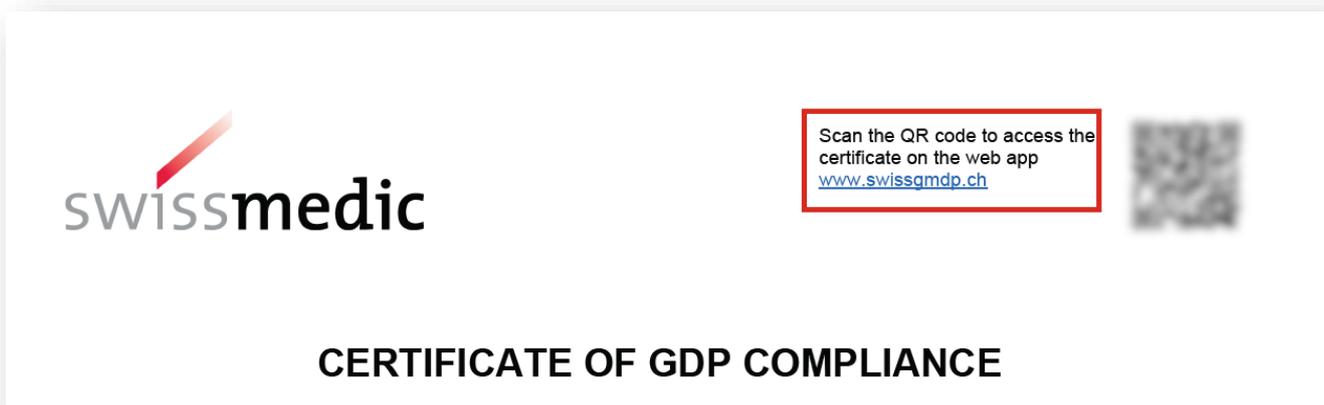
Test AG 3

Authorisation No.: 520000-123456789 Type: Medicinal Products incl. blood (MP) Address: Hallerstrasse 7 Postal Code: 3012 City: Bern

Sites - Match Found Inside Collapsible Section ▾

Site No.	Name	Address	Postal Code	City	Certificate No.	Compliance Status	Actions
1112345	Test AG 3	Hallerstrasse 7	3012	Bern	7654321	✓	 
1234112	Test AG 3	Erlachstrasse 8	3012	Bern	1001515	✓	 
1312123	Test AG 3	Freiburgstrasse 139	3008	Bern	1100777	✓	 

2. By clicking on the link in the header of a PDF certificate document;



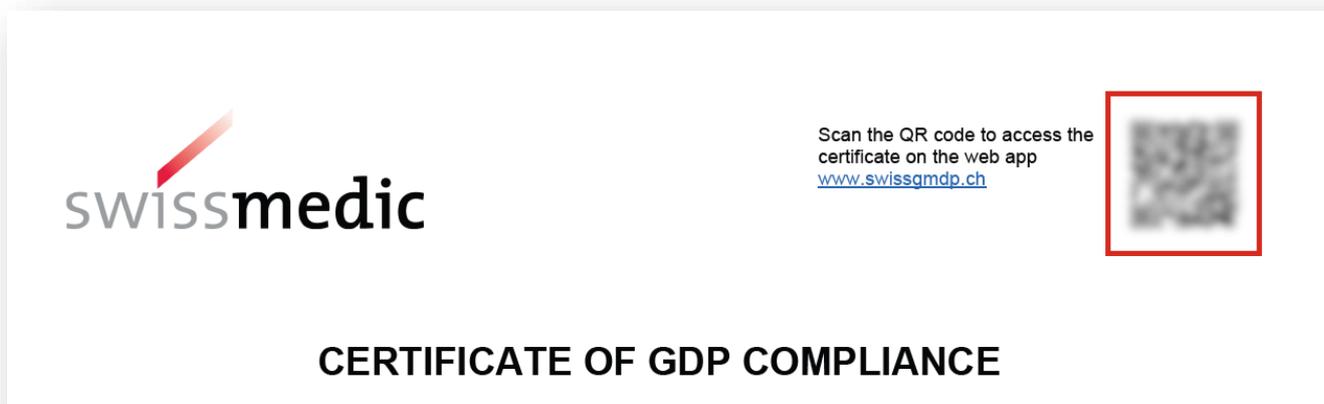


Scan the QR code to access the certificate on the web app
www.swissgmdp.ch



CERTIFICATE OF GDP COMPLIANCE

3. or by scanning the QR code provided on the certificate document.





Scan the QR code to access the certificate on the web app
www.swissgmdp.ch



CERTIFICATE OF GDP COMPLIANCE

When you click the action button or link, or scan the QR code, you'll be redirected to the detail view of the selected site, where you can access all site details.

Test AG 3 Copy Link Download Certificate(s)

Establishment Licence Holder Details

Name
Test AG 3

Address
Hallerstrasse 7

Postal Code
3012

City
Bern

Authorisation Number
520000-123456789

Type
Medicinal Products incl. blood (MP)

Site Details

Name
Test AG 3

Address
Erlachstrasse 8

Postal Code
3012

City
Bern

Site Number
1234112

Certificate Number
1001515

Date of last inspection (dd.mm.yyyy)
25.05.2022

Compliance Status
✓ Compliant

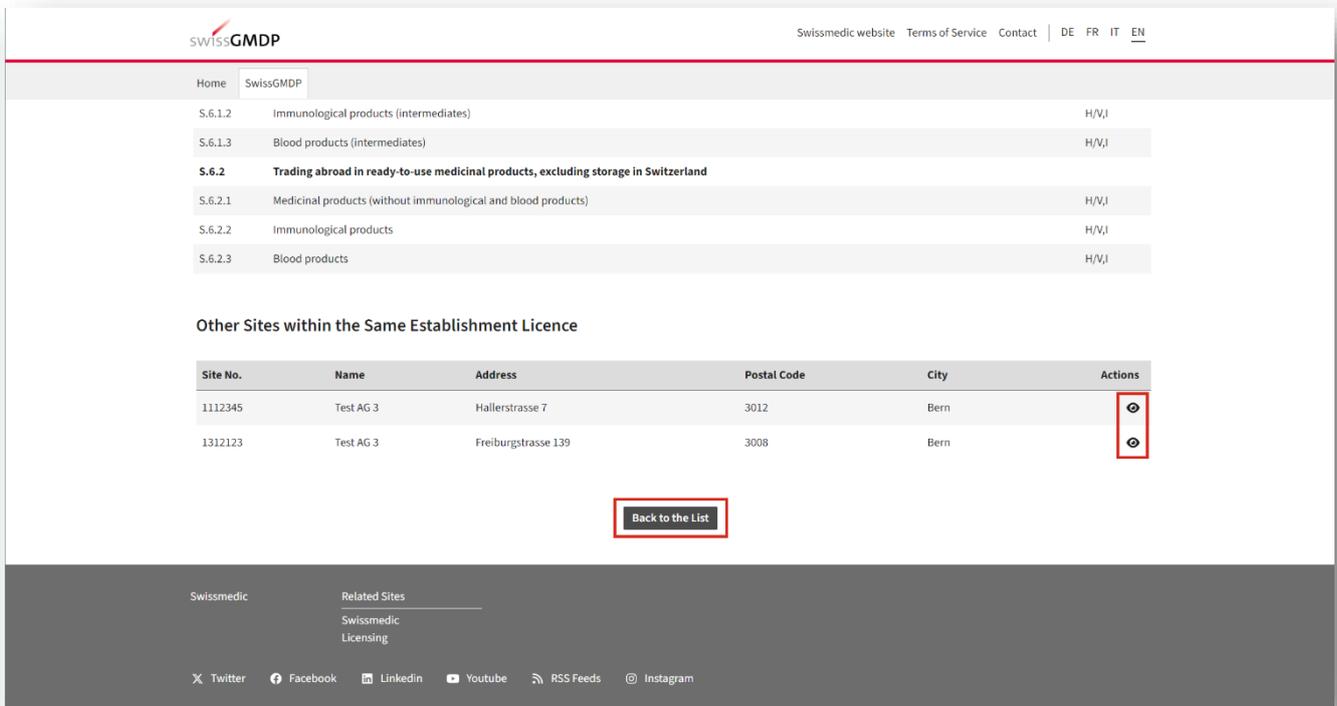
Furthermore, in the top right-hand corner, there's a *Download Certificate(s)* button. Clicking it triggers a modal to appear, allowing you to select and download the available certificate documents for the chosen site (see also chapter 2.4).

Underneath the establishment licence holder details and site details, you will find the authorisation scope table. This table displays all authorised operations of the site. Hovering over each scope will reveal a tooltip with its full description.

Authorisation Scope

No.	Operations	Scope
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.1	Sterile Products	Human investigational medicinal products
1.1.3	Batch certification (technical release)	
1.2	Non-sterile products	
1.2.1	Non-sterile products (processing operations for the following dosage forms)	
1.2.1.1	Capsules, hard shell	
1.2.1.8	Other solid dosage forms	
1.2.1.13	Tablets	
1.2.1.17	Other non-sterile medicinal product: PLGA-Microparticles	
1.2.2	Batch certification (technical release)	
1.5	Packaging	
1.5.1	Primary packaging	
1.5.1.1	Capsules, hard shell	
1.5.1.2	Capsules, soft shell	

Towards the end of the detail view, you will find a table listing all sites within the same establishment licence. You can access the detailed view of these sites by clicking the *View Details* action button.



The screenshot shows the SWISSGMDP website interface. At the top, there is a navigation bar with the SWISSGMDP logo and links for 'Swissmedic website', 'Terms of Service', 'Contact', and language options 'DE', 'FR', 'IT', 'EN'. Below the navigation bar, there is a breadcrumb trail: 'Home' > 'SwissGMDP'. The main content area displays a list of medicinal products under various categories (S.6.1.2, S.6.1.3, S.6.2, S.6.2.1, S.6.2.2, S.6.2.3). Below this list, there is a section titled 'Other Sites within the Same Establishment Licence' which contains a table with the following data:

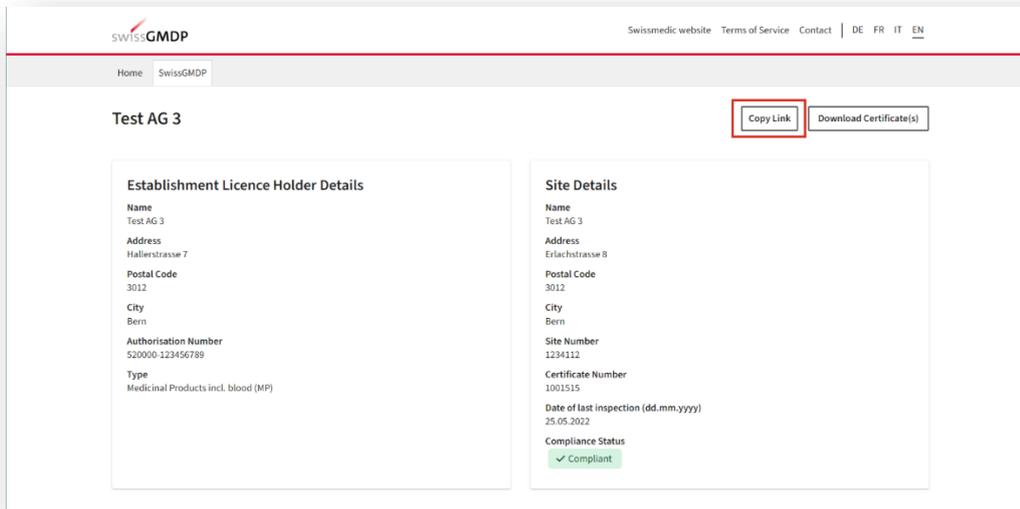
Site No.	Name	Address	Postal Code	City	Actions
1112345	Test AG 3	Hallerstrasse 7	3012	Bern	
1312123	Test AG 3	Freiburgstrasse 139	3008	Bern	

Below the table, there is a button labeled 'Back to the List' which is highlighted with a red box. At the bottom of the page, there is a footer with social media links for Twitter, Facebook, LinkedIn, Youtube, RSS Feeds, and Instagram, along with a 'Related Sites' section for 'Swissmedic Licensing'.

Clicking the "Back to the List" button will redirect you to the establishment licence holder list, with the previously opened site highlighted for easy identification.

2.8 Copy & share detail view link for a site

In the detail view of a specific site, you can click the *Copy Link* button in the top right corner to directly copy the link to this view to your clipboard, simplifying the process of sharing specific site links with collaborators.



3 Changes to the previous version

- None, new document